AMENDED IN ASSEMBLY MAY 5, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 1187

Introduced by Assembly Member Wolk

February 22, 2005

~~An act to amend Section 119400 of the Health and Safety Code, relating to drug marketing practices.~~ *An act relating to medical devices.*

LEGISLATIVE COUNSEL'S DIGEST

AB 1187, as amended, Wolk. ~~Drug marketing~~ *Marketing* practices: ~~dangerous drug.~~ *medical devices.*

Existing law, commencing July 1, 2005, requires every pharmaceutical company to adopt a Comprehensive Compliance Program that includes policies related to interactions with health care professionals and limits on gifts or incentives provided to medical or health professionals. For purposes of these drug marketing provisions, "dangerous drug" is defined to include, among other things, a drug or device that, pursuant to federal or state law, may be dispensed only by prescription, or that is furnished pursuant to specified provisions of law.

~~This bill would delete device from this definition of "dangerous drug."~~

This bill would declare the intent of the Legislature to subsequently amend this bill to include provisions to address medical device marketing practices.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) Existing state law, commencing July 1, 2005, requires every pharmaceutical company to adopt a compliance program that includes policies relating to interactions with health care professionals that are based on the United States Department of Health and Human Services Office of Inspector General (OIG) Guidelines for Pharmaceutical Companies and the Pharmaceutical Research and Manufacturers of America (PhRMA) "Code on Interactions with Health Care Professionals," dated July 1, 2002.

(b) A single reference in the law to "devices" under the definition of "dangerous drugs" creates confusion for medical device companies as to whether they are required to comply with the law's requirements.

(c) Medical devices, including, but not limited to, artificial spinal disks, cardiac stents, implantable defibrillators, and implantable devices to treat strokes are developed, marketed and used very differently from drugs and, therefore, interactions with health care professionals are also very different.

(d) Unlike drugs developed in laboratories, devices are developed through collaboration between health care professionals and device manufacturers.

(e) Whereas physicians can gain all needed information on a drug from the labeling information, it is crucial—and sometimes required by the federal FDA—for manufacturers to expose, educate, and train health care professionals on a device's unique characteristics relating to its use or implantation.

(f) Unlike the pharmaceutical industry, the medical device industry is dominated by small companies, with 90 percent of the industry having 100 or fewer employees, and the administrative requirements of the law impose a substantial burden on these innovative companies that do not have the scale and resources of very large pharmaceutical companies.

(g) While medical devices are different from drugs, there is a potential for marketing abuses; consequently, industry specific guidelines may be necessary.

(h) It is therefore the intent of the Legislature to subsequently amend this measure to include provisions to address those marketing practices.

~~SECTION 1. Section 119400 of the Health and Safety Code is amended to read:~~

~~119400. The following definitions shall apply for purposes of this chapter:~~

~~(a) "Dangerous drug" means any drug that is unsafe for self-use and includes either of the following:~~

~~(1) Any drug that bears the legend "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.~~

~~(2) Any drug that, pursuant to federal or state law, may be dispensed only by prescription, or that is furnished pursuant to Section 4006 of the Business and Professions Code. "Dangerous drug" does not include labeled veterinary drugs.~~

~~(b) "Medical or health professional" means any of the following:~~

~~(1) A person licensed by state law to prescribe drugs for human patients.~~

~~(2) A medical student.~~

~~(3) A member of a drug formulary committee.~~

~~(c) "Pharmaceutical company" means an entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of dangerous drugs, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis. "Pharmaceutical company" also means an entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of dangerous drugs. "Pharmaceutical company" also includes a person who engages in pharmaceutical detailing, promotional activities, or other marketing of a dangerous drug in this state on behalf of a pharmaceutical company. "Pharmaceutical company" does not include a licensed pharmacist.~~

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